

AMENDED IN ASSEMBLY APRIL 22, 2003
AMENDED IN ASSEMBLY MARCH 25, 2003
AMENDED IN ASSEMBLY MARCH 5, 2003

CALIFORNIA LEGISLATURE—2003–04 REGULAR SESSION

ASSEMBLY BILL

No. 103

Introduced by Assembly Members Reyes and Koretz
(Coauthors: Assembly Members Hancock and Lieber)
(Coauthors: Senators Chesbro, Romero, and Soto)

January 10, 2003

An act to add ~~Section 4168~~ *Sections 4168, 4169, and 4169.5* to the Business and Professions Code, relating to pharmaceuticals.

LEGISLATIVE COUNSEL'S DIGEST

AB 103, as amended, Reyes. Pharmaceuticals: marketing activities.

Existing law, the Pharmacy Law, regulates wholesalers and manufacturers of dangerous drugs and makes the California State Board of Pharmacy responsible for administering and enforcing the provisions of that law. ~~Under the Pharmacy Law, all revenue collected by the board is deposited into the Pharmacy Board Contingent Fund.~~ The Pharmacy Law makes a violation of its provisions punishable as a crime.

This bill would ~~require~~ *define “inappropriate marketing” and would prohibit* a pharmaceutical manufacturing company, as defined, ~~to annually disclose to the board certain information regarding the economic benefits the company provides in connection with its marketing activities, including disclosing the names of the recipients of~~

~~any benefits and the value, nature, and purpose of the benefits. The bill would also require the board to report Governor and the Legislature regarding these disclosures from annually giving any gift, fee, payment, subsidy, or other economic benefit, except as specified, that is more than the gift limit amount specified in regulations.~~

~~The bill would impose a civil penalty of \$10,000 for the violation of its disclosure requirements and would specify that awards obtained by the board be deposited into the Pharmacy Board Contingent Fund.~~

The bill, by specifying an additional ~~requirement~~ requirements under the Pharmacy Law, the violation of which is a crime, would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

- 1 ~~SECTION 1. Section 4168 is added to the Business and~~
- 2 *SECTION 1. Section 4168 is added to the Business and*
- 3 *Professions Code, to read:*
- 4 *4168. (a) It is unlawful for any person to engage in*
- 5 *inappropriate marketing of any dangerous drug or device to a*
- 6 *physician, hospital, nursing home, pharmacist, health benefit plan*
- 7 *administrator, or any other person in California authorized to*
- 8 *prescribe, dispense, or purchase dangerous drugs in this state.*
- 9 *(b) For purposes of this section, "inappropriate marketing"*
- 10 *means any action intended to entice a physician or other medical*
- 11 *provider to employ a dangerous drug or device in the treatment of*
- 12 *a patient by offering any of the following:*
- 13 *(1) Cash payments to physicians of any kind.*
- 14 *(2) Gifts to physicians that are not directly related to the benefit*
- 15 *of the patient or the practice of the physician related to the*
- 16 *dangerous drug or device.*
- 17 *(3) Any cost for litigation in relation to the prescription of a*
- 18 *dangerous drug or device.*

1 (4) Travel, meals, or lodging for the physician unless they are
2 associated with legitimate physician education.

3 SEC. 2. Section 4169 is added to the Business and Professions
4 Code, to read:

5 4169. (a) A pharmaceutical manufacturing company shall
6 not provide to a physician, hospital, nursing home, pharmacist,
7 health benefit plan administrator, or any other person in
8 California authorized to prescribe, dispense, or purchase
9 dangerous drugs in this state any gift, fee, payment, subsidy, or
10 other economic benefit in any calendar year in excess of the gift
11 limit amount as described in Section 18940.2 of Title 2 of the
12 California Code of Regulations, either directly or through its
13 pharmaceutical marketers or wholesale distributors, in
14 connection with detailing, promotional, or other marketing
15 activities.

16 (b) A physician, hospital, nursing home, pharmacist, health
17 benefit plan administrator, or any other person in California
18 authorized to prescribe, dispense, or purchase dangerous drugs in
19 this state shall not accept gifts, fees, payments, subsidies, or other
20 economic benefits in any calendar year with a total value greater
21 than the gift limit amount as described in Section 18940.2 of Title
22 2 of the California Code of Regulations, provided either directly
23 by a pharmaceutical manufacturing company or through its
24 pharmaceutical marketers or wholesale distributors, in
25 connection with detailing, promotional, or other marketing
26 activities.

27 (c) The following shall not be assessed as a gift as described in
28 subdivisions (a) and (b):

29 (1) A complimentary sample of a dangerous drug intended to
30 be furnished to a patient.

31 (2) The payment of reasonable compensation and
32 reimbursement of expenses in connection with a clinical trial of a
33 dangerous drug.

34 (3) Any economic benefit received through contracting for the
35 gross purchase of dangerous drugs or medical devices.

36 (d) The following definitions apply for purposes of this section:

37 (1) "Clinical trial" means an approved clinical trial conducted
38 in connection with a research study designed to answer specific
39 questions about vaccines, new therapies, or new ways of using
40 known treatments.

(2) *“Dangerous drug” means any drug that is unsafe for self-use and includes any of the following:*

(A) *Any drug that bears the legend “Caution: federal law prohibits dispensing without prescription,” “Rx only,” or words of similar import.*

(B) (i) *Any drug or device that, pursuant to federal or state law, may be dispensed only with a prescription, or that is furnished pursuant to Section 4006.*

(ii) *“Dangerous drug” does not include labeled veterinary drugs.*

(3) (A) *“Pharmaceutical manufacturing company” means an entity that is engaged in the production, preparation, propagation, compounding, conversion, or processing of dangerous drugs, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis.*

(B) *“Pharmaceutical manufacturing company” also means an entity engaged in the packaging, repackaging, labeling, relabeling, or distribution of dangerous drugs.*

(4) *“Pharmaceutical marketer” means a person who, while employed by or under contract to represent a pharmaceutical manufacturing company, engages in pharmaceutical detailing, promotional, or other marketing activities of a dangerous drug in this state to a physician, hospital, nursing home, pharmacist, health benefit plan administrator, or any other person authorized to prescribe, dispense, or purchase a dangerous drug.*

SEC. 3. *Section 4169.5 is added to the Business and Professions Code, to read:*

4169.5. (a) *Any pharmaceutical manufacturing company, physician, hospital, nursing home, pharmacist, health benefit plan administrator, or any other person in California authorized to prescribe, dispense, or purchase dangerous drugs in this state who willfully and knowingly violates any provision of Section 4168 or 4169 shall be liable for a civil penalty of not more than ten thousand dollars (\$10,000) for each violation. Each violation of these sections constitutes a separate offense for which the civil penalty may be assessed. The prevailing plaintiff in the action shall be awarded costs and reasonable attorney’s fees in addition to the civil penalty.*

(b) Nothing in Sections 4168 or 4169 shall be construed to impair or impede a licensing agency's authority under any other provision of law.

Professions Code, to read:

~~4168. (a) On or before January 1 of each year, a pharmaceutical manufacturing company shall disclose to the board the recipient name and value, nature, and purpose of any gift, fee, payment, subsidy, or other economic benefit it provided directly or through its pharmaceutical marketers or wholesale distributors in connection with detailing, promotional, or other marketing activities to a physician, hospital, nursing home, pharmacist, health benefit plan administrator, or any other person in California authorized to prescribe, dispense, or purchase dangerous drugs in this state. Disclosure shall be made on a form and in a manner prescribed by the board. The initial disclosure shall be made on or before January 1, 2005, for the period beginning on July 1, 2003, and ending June 30, 2004. The board shall report to the Governor and the Legislature on or before March 1 of each year, commencing in 2005, the information disclosed to it pursuant to this section.~~

~~(b) A pharmaceutical manufacturing company shall also disclose to the board, on or before October 1, 2004, and annually thereafter, the name and address of the individual responsible for the company's compliance with the provisions of this section.~~

~~(c) The board shall not disclose information identified as a trade secret by the pharmaceutical manufacturing company in its disclosure.~~

~~(d) The following shall be exempt from disclosure:~~

~~(1) A complimentary sample of a dangerous drug intended to be furnished to a patient.~~

~~(2) The payment of reasonable compensation and reimbursement of expenses in connection with a clinical trial.~~

~~(3) Any gift, fee, payment, subsidy, or other economic benefit having a value of less than twenty-five dollars (\$25).~~

~~(e) A civil penalty in the amount of ten thousand dollars (\$10,000) may be assessed for each violation of this section. Each failure to disclose constitutes a separate violation of this section for which the civil penalty may be assessed. The prevailing plaintiff in the action shall be awarded costs and reasonable attorney's fees in addition to the civil penalty. If the board is the prevailing~~

1 ~~plaintiff, the civil penalty, costs, and attorney's fees shall be~~
2 ~~deposited into the Pharmacy Board Contingent Fund.~~

3 ~~(f) The following definitions apply for purposes of this section:~~

4 ~~(1) "Clinical trial" means an approved clinical trial conducted~~
5 ~~in connection with a research study designed to answer specific~~
6 ~~questions about vaccines, new therapies, or new ways of using~~
7 ~~known treatments.~~

8 ~~(2) "Pharmaceutical manufacturing company" means an~~
9 ~~entity that is engaged in the production, preparation, propagation,~~
10 ~~compounding, conversion, or processing of dangerous drugs,~~
11 ~~either directly or indirectly, by extraction from substances of~~
12 ~~natural origin or independently by means of chemical synthesis or~~
13 ~~by a combination of extraction and chemical synthesis.~~
14 ~~"Pharmaceutical manufacturing company" also means an entity~~
15 ~~engaged in the packaging, repackaging, labeling, relabeling, or~~
16 ~~distribution of dangerous drugs.~~

17 ~~(3) "Pharmaceutical marketer" means a person who, while~~
18 ~~employed by or under contract to represent a pharmaceutical~~
19 ~~manufacturing company, engages in pharmaceutical detailing,~~
20 ~~promotional activities, or other marketing of a dangerous drug in~~
21 ~~this state to a physician, hospital, nursing home, pharmacist, health~~
22 ~~benefit plan administrator, or any other person authorized to~~
23 ~~prescribe, dispense, or purchase a dangerous drug.~~

24 ~~(4) "Dangerous drug" means any drug that is unsafe for~~
25 ~~self-use and includes any of the following:~~

26 ~~(A) Any drug that bears the legend "Caution: federal law~~
27 ~~prohibits dispensing without prescription," "Rx only," or words~~
28 ~~of similar import.~~

29 ~~(B) Any drug or device that, pursuant to federal or state law,~~
30 ~~may be dispensed only on prescription, or that is furnished~~
31 ~~pursuant to Section 4006.~~

32 ~~"Dangerous drug" does not include labeled veterinary drugs.~~

33 ~~SEC. 2.~~

34 *SEC. 4.* No reimbursement is required by this act pursuant to
35 Section 6 of Article XIII B of the California Constitution because
36 the only costs that may be incurred by a local agency or school
37 district will be incurred because this act creates a new crime or
38 infraction, eliminates a crime or infraction, or changes the penalty
39 for a crime or infraction, within the meaning of Section 17556 of
40 the Government Code, or changes the definition of a crime within

1 the meaning of Section 6 of Article XIII B of the California
2 Constitution.

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